REMARKS

In the Office Action of May 1, 2006, the Examiner maintained the rejection of claims 1-3, 15, 17-19, and 40 under 35 U.S.C. § 102(a) for being anticipated by Roberts (WO 94/22476).

Applicants maintain the position that Roberts failed to provide an enabling disclosure of a low dose vaccine comprising multicomponent clostridial antigens with M.bovis. None the less, for the purpose of advancing the prosecution of this application, Applicants have presently amended the claims to be directed to vaccines wherein the adjuvant is a polymer adjuvant that functions by releasing antigens slowly, which clearly distinguishes the presently claimed invention from that taught by Roberts.

Roberts sought to prevent severe persistent local reactions by using adjuvant that would be a "readily dispersible (*i.e.*, non-depot), soluble adjuvant[s], thereby avoiding chronic irritation at the injection site" (page 6, lines 14 and 15).

By contrast, the present invention achieves the reduction of elimination of site reactions by using low dose compositions. The claimed compositions and their use are distinguished from the teaching of Roberts by using a polymer adjuvant. As set forth by Applicants in their specification, "[p]referred herein are adjuvants that function by encapsulating antigens and releasing them slowly over a period of weeks or months. Preferably, the adjuvants are polymers, including block copolymers (alternatively referred to herein as polymer adjuvants). A specific example of the preferred adjuvant is carbopol." (page 15, lines 23-28). Formulation with the adjuvant is described using CARBOPOL. It is stated that the adjuvant is added to the inactivated whole culture at low pH. "The pH is then adjusted upward to approximate 7.0 with, say, sodium hydroxide (NaOH). This pH adjustment step allows for the protective antigen components of the

Cl.chauvoei to become encapsulated in the polymer adjuvant. Without being bound to any particular theory of the invention, it is believed the Cl. chauveoi antigens are released over a period of several weeks. Because of the slow release, these antigens do not cause the typical animal reaction. The long-term release caused an enhanced immune response by the vaccinated animal." (page 21, lines 2-10).

As noted by the Examiner, Roberts teaches compositions using dispersible (non-depot) soluble adjuvants (page 6, lines 13-18). Accordingly, Applicants' objective and invention is precisely the opposite of the approach taught by Roberts, which requires a "readily dispersible (*i.e.*, non-depot), soluble adjuvant,..." With the present amendments, the required adjuvant is a polymer adjuvant that functions by releasing adjuvants slowly, opposite to the teachings and objective of Roberts. Accordingly, the claims as presently amended are neither anticipated nor obvious in view of Roberts.

Claims 46-47 stand rejected under 35 U.S.C. §102(a) for being anticipated by Roberts.

For the reasons set forth above, with the present amendments, claims 46 and 47 are neither anticipated nor obvious in view of Roberts.

Claims 46 and 47 are objected to for being of improper dependent form.

It is presumed that the Examiner is objecting that the claims are directed to methods of immunizing an animal, whereas the claims on which they depend recite vaccines for cattle.

Although in the preamble the claimed vaccines are recited as being for cattle, there is nothing to prevent those vaccines for being used with any animal, and accordingly claims 46 and 47 are proper. However, for the purpose of advancing the prosecution of this application, claims 46 and 47 have been amended to be directed immunizing a bovine animal.

Claims 1-3, 15, 17-19, 40, and 46-47 are rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. The Examiner has objected that the claims are directed to at least six or at least seven clostridial components and concluded that there is no upper limit on the additional clostridial organisms that could be included.

It is clearly within the skill of the art to determine what clostridial organisms and how many could be effectively incorporated in the vaccine. Note that the vaccine claims are limited by the recitation of being "an immunogenically effective combination." None the less, in order to advance the prosecution of this application, Applicants have amended the claims to recite "immunogenically effective combination of the protective antigen components from six clostridial organisms" in claim 1,and "from seven clostridial organisms" in claim 2. In addition, claim 40 is amended to recite a similar composition comprising specific protective antigen components, listing eight specific clostridial organisms. Support for claim 40 is found in the specification and in, for example, claim 17 as previously presented. It may be noted that Applicants have provided in the examples methods for determining whether or not vaccine combinations are immunogenically effective.

Claims 46 and 47 stand rejected under 35 U.S.C. 112, second paragraph, for being indefinite. The Examiner objects that the preamble being drawn to a method for immunizing an animal is not commensurate with the preamble of the vaccine claim being recited as a vaccine for cattle.

Although Applicants believe the rejection is improper for the reason set forth above, in order to advance the prosecution of this application claims 46 and 47 have been amended to recite a method for immunizing a bovine animal.

In view of the above it is believed that claims 1-3, 15, 17-19, 40, and 46-48 recite a patentable improvement in the art and are in condition for allowance. Favorable action is solicited.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, she is invited to telephone Applicants' attorney at the number below.

Applicants hereby request a one-month extension to respond to the May 1, 2006 Office action, and authorize the Commissioner to charge Deposit Account No. **02-2334** for the corresponding extension fee. Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any

other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Respectfully submitted,

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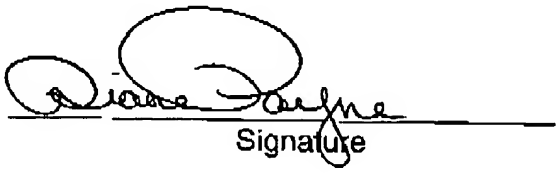

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Application of: Richard E. Parizek, *et al.*
For: A multicomponent vaccine containing clostridial...
Attorney Docket: 1-1995.184 US D1

Response to Office Action of May 1, 2006 (10 pages)
Facsimile Coversheet (1 page)
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